Remarks

Reconsideration of this Application is respectfully requested.

Upon entry of the foregoing amendment, claims 16-79 are pending in the application. Claim 77 has been amended to correct a typographical error. This change is believed to introduce no new matter, and entry of the amendment is respectfully requested.

Based on the above amendment and the following remarks, Applicants respectfully request that the Examiner reconsider all outstanding objections and rejections and that they be withdrawn.

Restriction Requirement

The Examiner stated that

> [n]ewly submitted claim 79 is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Elected Group I is directed at the polynucleotide product of SEQ ID NO:1. Newly added claim 79 is drawn to a material different polynucleotide product, SEQ ID NO:12. Since applicant has received a restriction requirement and elected Group I, claim 79 is withdrawn from consideration as being directed to a non-elected invention.

Page 2, § 2 of the Office Action dated September 22, 1999.

Applicants submit that a reasonable number of independent and distinct nucleotide sequences, usually up to ten, are permitted to be claimed in a single application. *See* 1192 O.G. 68 (November 19, 1996); and M.P.E.P. § 803.04. Although SEQ ID NO:1 and SEQ ID NO:12 may be patentably distinct, Applicants submit that they constitute a "reasonable number" of nucleotide sequences to be examined. Accordingly, withdrawal of the restriction requirement, with respect to SEQ ID NO:1 and SEQ ID NO:12, is respectfully requested.

Rejections under 35 U.S.C. § 112

The Examiner rejected claims 17, 19, 22-23, 26, 28-29, 34-35, 38, 40-41, 48-49, 52, 54-55, 62-63, 66, 68-69, 72-75 and 77 under 35 U.S.C. § 112, first paragraph, for allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventors had possession of the claimed invention at the time the application was filed.

Support for the recitations "nucleotides 15 to 392 of SEQ ID NO:1", as in claim 17, and "nucleotides 12 to 392 of SEQ ID NO:1", as in claim 19, can be found, *inter alia*, at page 11, lines 16-19, and in the sequence listing. Page 11, lines 16-19 of the specification recites, "(a) a nucleotide sequence encoding the BCSG1 polypeptide having the amino acid sequence in Figure 1 (SEQ ID NO:2); (b) a nucleotide sequence encoding the polypeptide having the amino acid sequence in SEQ ID NO:2, but lacking the N-terminal methionine." As shown in the sequence listing, nucleotides 12 to 392 of SEQ ID NO:1 encode a polypeptide having the amino acid sequence of SEQ ID NO:2; and nucleotides 15 to 392 of SEQ ID NO:1 encode a polypeptide having the amino acid sequence of SEQ ID NO:2, but lacking the N-terminal methionine. Applicants assert that this disclosure is sufficient to convey to one of ordinary skill in the art that the inventors had possession of the invention of claims 17 and 19 at the time the application was filed.

Support for "a heterologous polynucleotide," as in claims 22, 34, 48 and 62; and "said heterologous polynucleotide encodes a heterologous polypeptide," as in claims 23, 35, 49 and 63, can be found, *inter alia*, at page 10, lines 4-27; and at page 18, lines 2-29. The specification discloses, at page 10, lines 6-16, that the nucleic acid molecules of the invention may include

> the coding sequence for the polypeptide and additional sequences, such as those encoding an amino acid leader or secretory

> sequence, such as a pre- or pro- or prepro- protein sequence; the coding sequence of the polypeptide, with or without the aforementioned additional coding sequences, together with additional, non-coding sequences, including for example, but not limited to introns and non-coding 5' and 3' sequences, such as the transcribed, non-translated sequences that play a role in transcription, mRNA processing, including splicing and polyadenylation signals, for example - ribosome binding and stability of mRNA; an additional coding sequence which codes for additional amino acids, such as those which provide additional functionalities.

Applicants assert that the above passage, as well as the additional disclosure at page 10, lines 17-27 and at page 18, lines 2-29, is sufficient to convey to one of ordinary skill in the art that the inventors had possession, at the time of filing, of the invention of claims 22, 23, 34, 35, 48, 49, 62 and 63. For example, pre-, pro- and prepro-protein sequences; and non-coding sequences, such as introns and non-translated sequences that play a role in transcription, are sequences which may be heterologous polynucleotides. Further, "additional coding sequence which codes for additional amino acids," may be a heterologous polynucleotide encoding a heterologous polypeptide. Illustrative examples of such heterologous polypeptides are given at page 18, lines 2-29.

Support for "operably associated with a heterologous regulatory sequence," as in claims 26, 28, 38, 40, 52, 54, 66, and 68, can be found, *inter alia*, at page 10, lines 4-27; and at page14, line 27 to page 15, line 8. Page 14, line 27 to page 15, line 4, states that the nucleic acids, for example, when present in a vector

> should be operatively linked to an appropriate promoter, such as the phage lambda PL promoter, the *E. coli lac*, *trp* and *tac* promoters, the SV40 early and late promoters and promoters of retroviral LTRs, to name a few. Other suitable promoters will be known to the skilled artisan. The expression constructs will further contain sites for transcription initiation, termination and, in the transcribed region, a ribosome binding site for translation.

Applicants assert that this disclosure, along with the disclosure discussed above, is sufficient to convey to one of ordinary skill in the art that the inventors had possession of the invention of claims 26, 28, 38, 40, 52, 54, 66, and 68. For example, promoters and sites for transcription initiation and termination, and ribosome binding sites, are all regulatory sequences. Further regulatory sequences are discussed at page 10, lines 4-27, for example, splicing and polyadenylation signals.

Support for "except for one to thirty conservative amino acid substitutions," as in claim 72, and "wherein said substitutions is not more than 10," "5," or "3" as in claims 73, 74, and 75, respectively, can be found, *inter alia*, at page 20, line 6 to page 21, line 14. For example, the specification at page 20, lines 8-9, states the polypeptides include those in which "one or more of the amino acid residues are substituted with a conserved or non-conserved amino acid residue (preferably a conserved amino acid residue)." Table 1 on page 21 lists examples of conservative amino acid substitutions. Page 21, lines 14-15 states that the number of substitutions will not be more than "30, 25, 20, 15, 10, 5 or 3." Applicants assert that this disclosure is sufficient to convey to one of ordinary skill in the art that the inventors had possession of the invention of claims 72-75 at the time of filing.

Applicants have amended claim 77 to recite "nucleotides 12 to 392 of SEQ ID NO:1" instead of "nucleotides 18 to 392 of SEQ ID NO:1". As stated above, page 11, lines 16-19 and the sequence listing provide support for nucleotides 12 to 392 and 15 to 392 of SEQ ID NO:1. Applicants assert that this disclosure is sufficient to convey to one of ordinary skill in the art that the inventors had possession of the invention of claim 77 at the time of filing.

Accordingly, withdrawal of the rejection of claims 17, 19, 22-23, 26, 28-29, 34-35, 38, 40-41, 48-49, 52, 54-55, 62-53, 66, 68-69, 72-75 and 77 under 35 U.S.C. § 112, first paragraph, is respectfully requested.

The Examiner rejected claims 31-42 and 71-76 under 35 U.S.C. § 112, first paragraph, for alleged lack of written description regarding the ATCC Deposit. More specifically, the Examiner has required amendment of the specification to recite the date of the deposit and the complete name and address of the depository. Applicants would like to point out that the date of the deposit and name and address of the depository are listed in the specification at page 5, lines 17-20. The address was updated in an amendment filed July 23, 1999. Thus, no further amendment to the specification regarding the deposit is necessary.

Additionally, Applicants submit herewith a "Statement Concerning the Deposited DNA Clone," by which an attorney of record declares that the deposit was made under the terms of the Budapest Treaty, all restrictions upon public access to the deposit will be irrevocably removed upon the grant of a patent on this application, and that the deposit will be replaced if viable samples cannot be dispensed by the depository, as required by the Examiner. Accordingly, withdrawal of this rejection is respectfully requested.

Conclusion

All of the stated grounds of objection and rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding objections and rejections and that they be withdrawn. Applicants believe that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for

any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Prompt and favorable consideration of this Amendment and Reply is respectfully requested.

Respectfully submitted,

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